UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,297	05/09/2005	Alexandre Templier	0501-1135	1141

466   7590   11/30/2007

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ART UNIT	PAPER NUMBER
2128	

MAIL DATE	DELIVERY MODE
11/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

		Application No.	Applicant(s)
Office Action Summary		10/534,297	TEMPLIER ET AL.
		Examiner	Art Unit	
		Saif A. Alhija	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _09 May 2005_.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-16_ is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-16_ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on _09 May 2005_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a) ☒ All   b) ☐ Some * c) ☐ None of:

       1. ☒ Certified copies of the priority documents have been received.

       2. ☐ Certified copies of the priority documents have been received in Application No. _____.

       3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _8/9/05_.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

1.   Claims 1-16 have been presented for examination.

PRIORITY

2.   Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

3.   The information disclosure statement (IDS) submitted on 9 August 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner has considered the IDS as to the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

MPEP 2106 recites:

The claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result" State Street 149 F.3d at 1373, 47 USPQ2d at 1601-02. A process that consists solely of the manipulation of an abstract idea is not concrete or tangibles. See In re Warmerdam, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed.Cir. 1994). See also Schrader, 22 F.3d at 295, 30 USPQ2d at 1459

4.   i)   **Claims 1-16 are rejected under 35 U.S.C. 101** because the claimed invention pre-empts the field in which it takes part. The claims fail to provide a tangible result, and there must be a practical application, by either

1) transforming (physical thing) or

2) by having the FINAL RESULT (not the steps) achieve or produce a useful (specific, substantial, AND credible), concrete (substantially repeatable/non-unpredictable), AND tangible (real world/non-abstract) result.

A claim that is so broad that it reads on both statutory and non-statutory subject matter, must be amended. A claim that recites a method/system that solely calculates a mathematical formula is not statutory.

The courts have also held that a claim may not preempt ideas, laws of nature or natural

phenomena. The concern over preemption was expressed as early as 1852. See Le Roy v. Tatham, 55 U.S.

(14 How.) 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; an original cause; a

motive; these cannot be patented, as no one can claim in either of them an exclusive right."); Funk Bros.

Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132, 76 USPQ 280, 282 (194.8) .

Accordingly, one may not patent every "substantial practical application" of an idea, law of nature

or natural phenomena because such a patent "in practical effect would be a patent on the [idea, law

of nature or natural phenomena] itself." Here the "method/system" claim is so abstract and

sweeping as to cover both known and unknown uses of the processing of evaluation data. The end

use may (i) vary from simple circuit analysis to population polling and (2) be performed through

any existing machinery or future-devised machinery or without any apparatus." Gottschalk v.

Benson, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972).

The claims as presented lack any particular application, and could potentially be applied to any

field that involves data analysis and could possibly be applied to in the future and the past, which pre-empts

the industry from further research in the area. This leads to a rejection under U.S.C. 101.

ii)   **Claims 1-16 are rejected** under 35 U.S.C. 101 because the claimed invention is directed to non-

statutory subject matter.

a)   The Courts have found that subject matter that is not a practical application or use of an

idea, a law of nature or a natural phenomenon is not patentable. As the Supreme Court has made clear, "

[a]n idea of itself is not patentable," Rubber-Tip Pencil Co. v. Howard, 20 U.S. (i Wall.) 498, 507 (1874);

taking several abstract ideas and manipulating them together adds nothing to the basic equation. In re

Warmerdam, 31 USPQ2d 1754 (Fed. Cir. 1994).

The claimed "method/system" appears to be no more than manipulation of data without any

application or tangible output, therefore the claims are rejected under 35 USC 101.

b)   Claims 10-16 further appears to recite a computer program. It should be noted that code

(i.e., a computer software program) does not do anything per se. Instead, it is the code stored on a

computer that, *when executed,* instructs the computer to perform various functions. The following

claim is a generic example of a proper computer program product claim;

A computer program product embodied on a computer-readable medium and comprising code

that, when executed, causes a computer to perform the following:

> Function A
> Function B
> Function C, etc...

Appropriate correction is required.

All claims dependent upon a rejected base claim are rejected by virtue of their dependency.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-16 are rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Claim 1 recites "entity is created as a function of the intrinsic characteristics of said entity." It is

unclear what is meant by the term entity or the intrinsic characteristic of the entity and further how an entity is

created based on a characteristic. This renders the claim vague and indefinite. Claim 1 is also rejected under 35

U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting

to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how an entity is created based on

a characteristic.

ii) Claim 1 recites "an initial state of said entity is created and acquired." It is unclear what is meant

by the state of an entity since as stated above it is unclear precisely what is meant by an entity. This renders the

claim vague and indefinite.

iii) Claim 1 recites "an action is created and acquired as a function of the initial state." It is unclear

how to determine the metes and bounds of the term action with respect to the claim. This renders the claim vague

and indefinite.

iv)   Claim 1 recites "the statistical data." There is insufficient antecedent basis for this limitation.

v)   The rejections above further apply to claim 10.

vi)   The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

The rejections presented in sections i-iv above are exemplary of the 112 2nd issues present in the claims.

Appropriate correction is required.

All claims dependent upon a rejected base claim are rejected by virtue of their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6.   Claims 1-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Bleicher "Clinical Trial Data Management System and Method", WO 99/63473.**

Regarding Claim 1:

The reference discloses Method for processing evaluation data comprising a data acquisition phase in which:

a) at least one entity is created as a function of the intrinsic characteristics of said entity,

b) an initial state of said entity is created and acquired,

c) an action is created and acquired as a function of the initial state, then

d) resultant states are created and acquired during the evolution of the state of said entity and at fixed times, said resultant states being at least a function of the initial state and the action;

a second phase of processing the data in which the statistical data is generated as a function of criteria fixed by following the structure of at least one of the events a), b), c) and d) of the acquisition phase.

(Due to the numerous 112 2nd rejections above the Examiner will proceed under the interpretation that claim 1, based on the specification of the instant application, is intended to recite clinical data evaluation of patients. This can be seen in the reference in at least Figures 1-4, as well as Pages 12, Paragraph 2, and Page 17, "CDM", "Clinical Project Manager", etc.)

Regarding Claim 2:

The reference discloses Method according to claim 1, characterized in that the data relative to each entity are stored in a first "Information" database, while the structure of the events is contained in a second independent "Metabase" database. **(Page 12, Lines 14-25)**

Regarding Claim 3:

The reference discloses Method according to claim 1, characterized in that the processing comprises a sampling stage in which a sub-population of given entities is selected. **(Figure 4A, Demographics)**

Regarding Claim 4:

The reference discloses Method according to claim 3, characterized in that the selection is carried out by choosing at least one variable in the structure of at least one event a), b), c) or d), and by allocating a given constraint to this variable. **(Figure 4A, for example gender, DOB, etc...)**

Regarding Claim 5:

The reference discloses Method according to claim 1, characterized in that the processing comprises an analysis stage in which statistical data is generated in the form of values, tables or graphs. **(Figure 4A)**

Regarding Claim 6:

The reference discloses Method according to claim 5, characterized in that the analysis is carried out by choosing at least one variable in the structure of at least one event a), b), c) or d). **(Figure 4A)**

Regarding Claim 7:

The reference discloses Method according to claim 1, characterized in that the events a), b), c) and d) are created in chronological order. **(Figure 1, elements 401-419, Pages 24, Paragraph 2)**

Regarding Claim 8:

The reference discloses Method according to claim 1, characterized in that acquisition is carried out by means of intuitive graphical interfaces. **(Figure 4A)**

Regarding Claim 9:

The reference discloses Method according to claim 1, characterized in that the structure of each event is controlled by the metabase. **(Figure 2, element 105)**

Regarding Claim 10:

The reference discloses System for processing evaluation data comprising the acquisition means for:

a) creating at least one entity as a function of the intrinsic characteristics of this entity,

b) creating and acquiring an initial state of said entity,

c) creating and acquiring an action as a function of the initial state, then

d) creating and acquiring, during the evolution of the state of said entity and at fixed times, resultant states, these resultant states being at least a function of the initial state and the action; and the

means for processing data to generate statistical data as a function of fixed criteria by following the structure of at least one of the events a), b), c) and d). **(See rejection for claim 1)**

Regarding Claim 11:

The reference discloses System according to claim 10, characterized in that it comprises a first "Information" database to store the data relative to each entity and a second independent "Metabase" database containing the structure of the events. **(See rejection for claim 2)**

Regarding Claim 12:

The reference discloses System according to claim 10, characterized in that the means of data processing comprise a sampling module to select a sub-population of given entities and an analysis module to generate statistical data in the form of values, tables or graphs. **(See rejection for claim 3)**

Regarding Claim 13:

The reference discloses System according to claim 11, characterized in that the acquisition and processing means consist of generic interfaces capable of exploring the structure of the events. **(Examiners note. The mere capability to do something is not considered a limitation and therefore not afforded patentable weight.) (See rejection for claim 8)**

Regarding Claim 14:

The reference discloses Method according to claim 2, characterized in that the processing comprises a sampling stage in which a sub-population of given entities is selected. **(See rejection for claim 3)**

Regarding Claim 15:

The reference discloses System according to claim 11, characterized in that the means of data processing comprise a sampling module to select a sub-population of given entities and an analysis module to generate statistical data in the form of values, tables or graphs. **(See rejection for claim 5)**

Regarding Claim 16:

The reference discloses System according to claim 12, characterized in that the acquisition and processing means consist of generic interfaces capable of exploring the structure of the events. **(Examiners note. The mere capability to do something is not considered a limitation and therefore not afforded patentable weight.) (See rejection for claim 8)**

Examiners Remarks

7.   i)   Examiner has cited particular columns and line numbers in the references applied to the claims for the convenience of the applicant. Although the specified citations are representative of the teachings of the art and are applied to specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the applicant in preparing responses, to fully consider the references in their entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

ii)   The Examiner respectfully requests, in the event the Applicants choose to amend or add new claims, that such claims and their limitations be directly mapped to the specification, which provides support for the subject matter. This will assist in expediting compact prosecution.

iii)   Further, the Examiner respectfully encourages Applicants to direct the specificity of their response with regards to this office action to the broadest reasonable interpretation of the claims as presented. This will avoid issues that would delay prosecution such as limitations not explicitly presented in the claims, intended use statements that carry no patentable weight, mere allegations of patentability, and novelty that is not clearly expressed.

iv)   The Examiner also respectfully requests Applicants, in the event they choose to amend, to supply a clean version of the presented claims in addition to the marked-up copy in order to avoid potential inaccuracies with the version of the claims that would be examined.

Conclusion
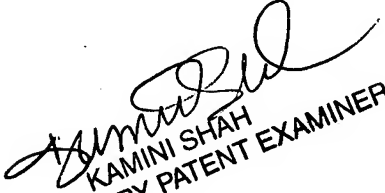
8.   All Claims are rejected.

9.   Any inquiry concerning this communication or earlier communications from the examiner should be

directed to Saif A. Alhija whose telephone number is (571) 272-8635. The examiner can normally be reached on M-

F, 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kamini Shah

can be reached on (571) 272-2279. The fax phone number for the organization where this application or proceeding

is assigned is (571) 273-8300. *Informal or draft communication, please label PROPOSED or DRAFT*, can be

additionally sent to the Examiners fax phone number, (571) 273-8635.

Information regarding the status of an application may be obtained from the Patent Application Information

Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR

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Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAA

November 27, 2007

KAMINI SHAH
SUPERVISORY PATENT EXAMINER